

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

APR 30 2009

Anita Meiklejohn Fish & Richardson 225 Franklin St. Boston MA 02110 In Re: Patent Term Extension
Application for
U.S. Patent No. 4,650,787

RE: SANVAR® (vapreotide acetate)

Dear Ms. Meiklejohn

A final interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,650,787 for a period of one year from the previously extended expiration date, i.e., until April 25, 2010. A copy of the Federal Register notice, published on April 22, 2009 at 74 Fed. Reg. 18352, regarding the issuance of the interim extension under 35 U.S.C. § 156(d)(5) is also enclosed. While a courtesy copy of this letter is being sent to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates which are pertinent to any filings before the FDA.

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at ((571) 272-7755 or at mary.till@uspto.gov by e-mail.

Mary C. **Jull** Legal Advisor

Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy

Food and Drug Administration

10903 New Hampshire Ave., Building 51, Rom 6222

Silver Spring, MD 20993-0002

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Debiovision Inc.
Request for Patent Term Extension
U.S. Patent No. 4,650,787

ORDER GRANTING INTERIM EXTENSION

On March 19, 2009, Debiovision Inc., an agent of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, patent owner, timely filed an application under 35 U.S.C. § 156(d)(5) for a fifth interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the active ingredient vapreotide acetate in the drug product Sanvar®. The application indicates that a New Drug Application for the human drug product Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional year as required by 35 U.S.C. § 156(d)(5)(B) and 35 U.S.C. § 156(d)(5)(C). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (April 25, 2009), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the extended expiration date of the patent, i.e., until April 25, 2010.

<u>04/15/09</u> Date

John J. **D**611

Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office

candidate may not be a registered foreign agent under the Foreign Agents Registration Act of 1938, as amended.

Evaluation of applications for membership in the U.S. Section by eligible individuals will be based on the following criteria:

- —A demonstrated commitment by the individual's company to the Brazilian market either through exports or investment.
- —A demonstrated strong interest in Brazil and its economic development.
- —The ability to offer a broad perspective and business experience to the discussions.
- —The ability to address cross-cutting issues that affect the entire business community.
- —The ability to initiate and be responsible for activities in which the Forum will be active.

Members will be selected on the basis of who will best carry out the objectives of the Forum as stated in the Terms of Reference establishing the U.S. Brazil CEO Forum. The U.S. Section of the Forum should also include members that represent a diversity of business sectors and geographic locations. To the extent possible, Section members also should represent a cross-section of small, medium, and large firms.

U.S. members will receive no compensation for their participation in Forum related activities. Individual members will be responsible for all travel and related expenses associated with their participation in the Forum, including attendance at Committee and Section meetings. Only appointed members may participate in official Forum meetings; substitutes and alternates will not be designated. U.S. members will normally serve for two-year terms, but may be reappointed.

To be considered for membership, please submit the following information as instructed in the ADDRESSES and DATES captions above: Name(s) and title(s) of the individual(s) requesting consideration; name and address of company's headquarters; location for incorporation; size of the company; size of company's export trade, investment, and nature of operations or interest in Brazil; and a brief statement of why the candidate should be considered, including information about the candidate's ability to initiate and be responsible for activities in which the Forum will be active. Applications will be considered as they are received. All candidates will be notified of whether they have been selected.

Dated: April 15, 2009.

Anne Driscoll,

Director for the Office of South America. [FR Doc. E9-9292 Filed 4-21-09; 8:45 am] BILLING CODE P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2009-0016]

Grant of Interim Extension of the Term of U.S. Patent No. 4,650,787; Sanvar®

AGENCY: United States Patent and Trademark Office.

ACTION: Notice of interim patent term

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension under 35 U.S.C. 156(d)(5) for a fifth one-year interim extension of the term of U.S. Patent No. 4,650,787.

FOR FURTHER INFORMATION CONTACT:

Mary C. Till by telephone at (571) 272–7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to her attention at (571) 273–7755, or by e-mail to Mary. Till@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On March 19, 2009, Debiovision Inc., the exclusive agent of Debiopharm S.A. and Debio Recherche Pharmaceutique S.A., who is the exclusive licensee of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, the patent owner, timely filed an application under 35 U.S.C. 156(d)(5) for a fifth interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the human drug product Sanvar® (vapreotide acetate). The application indicates that a New Drug Application for the human drug product Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for an additional one year as required by 35 U.S.C. 156(d)(5)(B) and 35 U.S.C. 156(d)(5)(C). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (April 25, 2009), a fifth interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A fifth interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the extended expiration date of the patent, i.e., until April 25, 2010.

April 25, 2010. April 15, 2009.

John J. Doll,

Acting Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. [FR Doc. E9–9145 Filed 4–21–09; 8:45 am] BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XO70

Incidental Taking of Marine Mammals; Taking of Marine Mammals Incidental to the Explosive Removal of Offshore Structures in the Gulf of Mexico

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of letters of authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA) and implementing regulations, notification is hereby given that NMFS has issued one-year Letters of Authorization (LOA) to take marine mammals incidental to the explosive removal of offshore oil and gas structures (EROS) in the Gulf of Mexico.

DATES: These authorizations are effective from May 15, 2009 through May 14, 2010.

ADDRESSES: The application and LOAs are available for review by writing to P. Michael Payne, Chief, Permits, Conservation, and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3235 or by telephoning the